



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/737,350 Docket No.: 112418.149 US2/  
AUR-011US  
Applicant: Elias Georges *et al.* Cust. No. 23483  
Date Filed: December 15, 2003 Conf. No.: 6000  
Art Unit: 1642 Examiner: Judy Lille Tidwell  
Title: **HSC70 Directed Diagnostics and Therapeutics for Multidrug Resistant Neoplastic Disease**

**CERTIFICATION UNDER 37 C.F.R. § 1.8**

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail under 37 C.F.R. § 1.8 with sufficient postage on the date indicated below and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

May 2, 2006  
Date of Deposit

Farah Bushashia  
Farah Bushashia

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO RESTRICTION REQUIREMENT**

Dear Madam:

Applicants hereby respond to the Restriction Requirement dated *March 2, 2006*.

**Remarks** begin on page 2 of this paper.

**Conclusions** begin on page 3 of this paper.

### **Election**

In response to the Restriction Requirement, Applicants elect, with traverse, **Group I, claims 1-9**, which is drawn to a method of detecting multi-drug resistance or multi-drug resistance potential in a test neoplastic cell comprising measuring a level of cell surface-expressed HSC70 protein and comparing the level of cell surface-expressed HSC70 protein.

A restriction requirement requires that the Examiner establish (A) the inventions are independent, *and* (B) the examination of the inventions will impose a serious burden on the Examiner (see MPEP § 803). However, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions (see MPEP § 803).

Applicants respectfully aver that examination of Groups I, II, X, and XI together would not impose a serious burden on the Examiner. Applicants respectfully assert that Groups I, II, X, and XI should be regrouped because the inventions are directed to similar methods of detecting the level of HSC70 expressed on the cell surface of a test neoplastic cell. The inventions utilize binding agents to detect the expression of cell surface-expressed HSC70 on test neoplastic cells (see Application, pg. 21, lines 6-11; pg. 31, lines 3-28). In the examination of Groups I, II, X, and XI, the examination of the claims would require a search for methods utilizing binding agents to detect cell surface-expressed HSC70. For the purposes of the search, it should not matter that the method attempts to detect the presence of a test neoplastic cell or a test multi-drug resistant cell. Regardless of the different objectives of the inventions in Groups I, II, X, and XI, the examination would require a search for binding agents specific for HSC70.

Accordingly, Applicants respectfully request that Groups I, II, X, and XI be regrouped and examined together.

### **Species Election**

At page 8 of the Office Action, Applicants are requested to further elect a species from each of genres 1, 2, and 3 for **Group I**. The Office Action further states that the invention groups contain multiple generic claims in which the alternative limitations were independent or distinct inventions that do not share a common utility or substantial structural feature (see Office Action, *Species Election*, pg. 9).

In response to the Election Requirement applicable to **Group I** identified on page 8 of the Office Action, Applicants elect, with traverse, a leukemia cell, blood, and HL60.

According to MPEP § 803.02, it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. Unity of invention exists where compositions included in the Markush group 1) share a common utility, and 2) share *a substantial structural feature*.

Applicants respectfully assert that the species of genuses 1 and 3 share a common utility and a substantial structural feature essential to the utility, and the species should be examined together. Genuses 1 and 3 encompass neoplastic cells and cell lines. The neoplastic cells and cell lines share the same utility in that the neoplastic cells and cell lines are utilized in the method of detecting multidrug resistance. In addition, the neoplastic cells and cell lines share the structural feature of being neoplastic cells that have multidrug resistance potential. This feature is essential to the method of detecting multidrug resistance in neoplastic cells. Therefore, genuses 1 and 3 share a common utility and a substantial structural feature essential to the utility.

For the foregoing reasons, Applicants respectfully request that the Election Requirement be reconsidered, and grouped such that all species are examined together.

In addition, Applicants respectfully request that additional species, which are written in dependent form or otherwise include all limitations of a generic claim, be examined in the instant application (see 37 CFR 1.141). Applicants further request that where product claims are allowed, any withdrawn process claims that depend from or otherwise include all limitations of the allowed product claims be rejoined in accordance with MPEP § 821.04.

### **Conclusion**

Applicants respectfully request that the Restriction Requirement be reconsidered and withdrawn. In its place, Applicants respectfully request that Groups I, II, X, and XI be regrouped and examined together. In addition, as to the Election Requirement concerning genuses 1, 2, and 3 for **Group I**, Applicants respectfully request that the Election be reconsidered and all species be examined together.

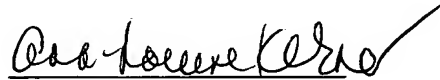
The time for responding to this action has been extended to May 2, 2006 by the accompanying Petition for a One Month Extension of Time and payment of fee. No additional fees are believed to be due in connection with this response. However, if any additional fees are

due, please charge any underpayments or credit any overpayments to Deposit Account No. 08-0219.

If there are any questions regarding this matter, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

Date: May 2, 2006

A handwritten signature in black ink, appearing to read "Ann-Louise Kerner", with a long horizontal stroke extending to the right.

Ann-Louise Kerner, Ph.D.  
Registration No. 33,523

WILMER CUTLER PICKERING HALE AND DORR LLP  
60 State Street  
Boston, MA 02109  
Tel: (617) 526-6192  
Fax: (617) 526-5000